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OSHA'S ANALYSIS OF ETS

1. Introduction and Overview

OSHA's Proposed Rule states that "before the Secretary can promulgate any permanent health or safety standard, he must find that a significant risk of harm is present in the workplace and that the new standard is reasonably necessary to reduce or eliminate that risk. Industrial Union Department, AFL-CIO v. American Petroleum Institute, 444 U.S. 607, 639-642 (1980) (Benzene)." 59 Fed Reg. 16000. In an attempt to establish significant risk for ETS, the Proposed Rule reviews various disease endpoints reportedly associated with ETS, including (i) irritation, (ii) pulmonary effects (other than cancer) in adults, (iii) cardiovascular disease, (iv) reproductive effects and (v) lung cancer. In addition, characteristics of mainstream smoke (the smoke to which the smoker is exposed) and sidestream smoke (the smoke from the burning tip of the cigarette) are enumerated, and a select number of studies on ambient exposures to ETS constituents in the workplace are examined. Risk analyses for lung cancer and cardiovascular disease among nonsmokers in the workplace are presented. The risk analyses are based upon single epidemiologic studies that are then applied to estimates of mortality for the total nonsmoking workforce in the U.S.

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OSHA fails to demonstrate a significant risk of material impairment for any disease endpoint among nonsmokers reportedly exposed to ETS in the workplace. Particularly, OSHA fails to establish that existing exposures to ETS in the workplace pose a significant risk of material impairment to the health of nonsmokers. Failure to establish significant risk at current exposure levels is precisely the reason for which the U.S. Court of Appeals in 1992 vacated OSHA's Air Contaminants Standard. (See: American Federation of Labor and Congress of Industrial Organizations v. Occupational Safety and Health Administration, 965 F.2d 962 at 20.) Moreover, in 1991 OSHA acknowledged that it "does not have adequate information on the current level of exposure to ambient tobacco smoke in workplaces to accurately assess the existing level of occupational risk." Secretary's Response at 6, ASH v. OSHA. (Emphasis added). The data cited in OSHA's Proposed Rule do not remedy that deficiency.

OSHA's analysis of "significant risk" for ETS is based upon two epidemiologic studies in which ETS exposures are not measured directly. ETS exposures were estimated in the two studies by individual recall of exposure. Accurate quantitative measures of exposure cannot be ascertained through those kinds of studies. **No measured ambient exposure data for ETS are included in OSHA's estimate of risk due to ETS in the workplace.** Thus, OSHA offers an

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analysis of risk and a proposal for the complete elimination of ETS in the workplace **without reference to any measured exposure data.**

However, studies that report measured data for constituents of ETS in the air of indoor work environments are currently available. OSHA's discussion of such studies is limited, selective and unrepresentative of current ETS exposure data. Indeed, OSHA's Proposed Rule does not reference a single ambient air monitoring study for the workplace published after 1991, the same year in which OSHA admitted that it had no adequate data on "current levels of exposure" for ETS. 59 Fed Reg. 15990-1.

The Proposed Rule states that "estimating the risk from exposure to ETS requires the use of some measure of the extent of exposure . . . ." 59 Fed Reg. 15997. OSHA acknowledges failure to integrate ambient ETS exposure data into its analysis of significant risk and states that "since there is no definition of, nor an established method for quantifying, exposure, it is not possible to determine a 'dose limit' that would eliminate significant risks." 59 Fed Reg. 16001. As will be demonstrated in the analysis that follows, current exposure data on ETS levels in the workplace do not support the conclusion that ETS poses a "significant risk" to nonsmoking workers.

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The Occupational Safety and Health Act of 1970 requires the Secretary of Labor to develop a standard "that most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity . . ." 59 Fed Reg. 16007-8 (emphasis added). While the interpretation of what constitutes "best available evidence" may be an open question, it is incumbent upon OSHA to at least consider available data on workplace exposures to ETS, as well as all available data on health effects that are associated specifically with workplace exposures to ETS. OSHA's Proposed Rule does neither. It uncritically accepts, without discussion of quality or obvious weaknesses, one epidemiologic study on ETS to determine "significant risk" of lung cancer in the workplace. 59 Fed Reg. 15995. The data from 13 other available studies on nonsmoker lung cancer in the workplace, eight of which are from the U.S, are ignored. The Proposed Rule also utilizes a single epidemiologic study on cardiovascular disease (CVD) that deals with spousal smoking in the home to generate "significant risk," while ignoring available studies on reported ETS exposures and CVD in the workplace. 59 Fed Reg. 15995. The Proposed Rule bases its "exposure assessment" for ETS upon a select, outdated and unrepresentative group of ambient air monitoring studies, some of which do not deal with workplace exposures to ETS at all. 59 Fed Reg. 15990-2. OSHA's analyses will be discussed in the following sections.

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1. OSHA's Discussion of Tobacco Smoke Constituents Does Not Establish that ETS is Carcinogenic

OSHA's Proposed Rule on general IAQ does not include ETS because, according to OSHA, "the carcinogenicity of ETS discounts the use of general ventilation as an engineering control for this contaminant." 59 Fed Reg. 15992. OSHA's attempt to demonstrate the "carcinogenicity" of ETS takes the form of an argument from analogy from mainstream smoke (the smoke to which the active smoker is exposed) to ETS. OSHA claims that ETS is chemically similar to mainstream smoke, and that "carcinogens" reportedly identified in mainstream smoke are also present in ETS. 59 Fed Reg. 15979.

The Proposed Rule presents a table of substances labeled "Table II-2: 43 Chemical Compounds Identified in Tobacco Smoke for Which There is 'Sufficient Evidence' of Carcinogenicity in Humans or Animals." 59 Fed Reg. 15979-80. The 43 compounds listed therein are neither discussed nor reviewed in the Proposed Rule. Moreover, the Proposed Rule concedes that:

(1) Few of the substances identified as constituents of tobacco smoke (in the "list of 43") have been identified in ETS, i.e., "few of these individual [inhalational] constituents [imputed to ETS] have been identified and characterized." 59 Fed Reg. 15987;

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(2) The substances listed are also derived from other sources, i.e., "most of the identified carcinogenic components [in the list of 43] are not unique to ETS." 59 Fed Reg. 15998;

(3) Individual substances responsible for the alleged "carcinogenicity" of tobacco smoke have never been identified, i.e., "the mechanism of carcinogenicity from exposure to ETS is not known." 59 Fed Reg. 15998.

The so-called list of "43 carcinogens in tobacco smoke" has been challenged in the scientific literature.[1-4] One commentator notes:

> Many of these 43 MS [mainstream smoke] and/or tobacco components should be excluded from the list on the basis of published data on their tumorigenicity (or lack of it) in laboratory animals at levels determined in MS, their lack of tumorigenicity in most instances on inhalation, and the equivocal evidence of their tumorigenicity in humans at levels in MS. . . .
>
> . . . Only five of the 43 components have produced respiratory tract tumors in laboratory animals exposed to the component via inhalation. Many have never been tested in an inhalation system. One component of great interest, "benzo[a]pyrene," has only produced lung carcinoma via inhalation in animals at an extraordinary massive dose, a finding classified as "equivocal." (RTECS, 1987).[1]

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One of the few substances on "the list of 43" that has been tested via animal inhalation, nickel, has reportedly generated human-type lung cancers.[1] Nickel is not characteristic of tobacco smoke. It was tested for carcinogenicity at exposure levels far in excess of those found in the workplace, the environment or in tobacco smoke. For example, it has been estimated that 40,000 cigarettes burning simultaneously in a one hundred cubic meter enclosure would be required in order to generate a level of exposure to nickel equivalent to the Permissible Exposure Limit (PEL) established by OSHA.[2-4]

The "list of 43" constituents was developed in the 1970s, and it has been suggested that "many of the listed components are not relevant to those that would be found if the analysis were conducted on more recent cigarettes."[1] This is particularly true of the substances Dibenz(a,h)acridine and Dibenz(a,h)anthracéne. N'-nitrosonornicotine appears to be the only constituent characteristic of tobacco smoke from the "list of 43"; most of the constituents on the list, although theoretically identifiable, have never been identified in ETS (e.g., arsenic, chromium, etc.).[3]

Most of the substances were tested for carcinogenicity in animals through means other than inhalation. Skin painting of several components reportedly resulted in skin tumors, and neoplasms were reported in animals through ingestion and injection

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of various constituents. Several of the substances, e.g., benzene, formaldehyde and nitrosodiethylamine, reportedly produced neoplasms in areas other than the lung.[3] (Epidemiologic studies of workers report increased risks of leukemia by benzene; liver cancer by vinyl chloride; and urinary bladder cancer by 4-aminobiphenyl and 2-naphthylamine.)

Neither nicotine nor cotinine, the two substances selected by OSHA as biologic markers for exposure to ETS, are indicators of exposure to any of the constituents on the "list of 43." 59 Fed Reg. 15974, 15991, 15998. Neither substance is itself a "suspect carcinogen."[5] OSHA concedes that, since the constituents on the list of 43 are not unique to ETS, "direct measurement of the carcinogenic components or related biomarkers in biological fluids would not provide a unique measure of exposure from ETS." 59 Fed Reg. 15998. OSHA explicitly rejects one group of nine constituents on the "list of 43," the polycyclic aromatic hydrocarbons (PAHs), as candidate biomarkers precisely because they are found in low concentrations in tobacco smoke and because they are not unique to ETS. 59 Fed Reg. 15998.

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2. Mainstream and Sidestream Smoke Comparisons Are Not Relevant to ETS

The Proposed Rule presents two additional tables of constituents ascribed to tobacco smoke. 59 Fed Reg. 15987-8. The tables provide a comparison of the amount of each constituent reported in mainstream smoke with the amount reported for the constituent in sidestream smoke (the smoke directly at the burning tip of a cigarette). OSHA's argument is that if constituent levels in sidestream and mainstream smoke are compared, quantities are greater in sidestream smoke. However, the relevance of these comparisons to ETS is questionable.

ETS is not the same as either mainstream or sidestream smoke.[1, 6-9] ETS is an aged and diluted mixture of sidestream and exhaled mainstream smoke; ETS is a dynamic, ever-changing mixture that undergoes chemical transformations and physical changes as it ages and is diluted in the air.[1, 6-7] As one researcher in tobacco smoke chemistry has observed, "there are profound physical and quantitative chemical differences" among the three kinds of smoke (mainstream smoke, sidestream smoke and ETS).[1] There are differences in physical and chemical properties and in relative concentrations of constituents. Studies indicate that constituents in ETS are hundreds to thousands of times more dilute than either sidestream or mainstream smoke.[8-9] Concentrations of ETS constituents in real-life situations are often below the limits of

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detection and measurement for even the most sensitive air monitors. Often, the contributions of ETS constituents to the ambient air are indistinguishable from background levels of the same constituents generated by other sources.[8]

OSHA's strategy of comparing mainstream and sidestream smoke ignores the profound effect of dilution in the ambient air upon tobacco smoke constituents. As two tobacco smoke chemists report:

> The important question is not the ratio of sidestream/mainstream but rather what is the concentration of the constituent in the indoor environment and how does it compare to levels from sources other than ETS. Studies based solely on observations of fresh sidestream, are highly and unrealistically concentrated ETS should take into account the possible differences between these smokes and ETS found in real life situations.[6]

Similarly, the 1986 Report of the Surgeon General notes: " . . . SS [sidestream smoke] characteristics, as measured in chamber, do not represent those of ETS, as inhaled by the nonsmoker under non-experimental conditions."[10]

OSHA's tables of tobacco smoke constituents do not present levels reported for ETS. The relevance of OSHA's mainstream/sidestream smoke comparisons to workplace exposure levels of ETS is therefore questionable.

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3. Elimination of ETS Exposures in the Workplace Will Not Eliminate Nonsmoker Exposure to Carcinogens; Carcinogens Imputed to ETS by OSHA Have Permissible Exposure Limits, Yet OSHA Establishes a "No-Exposure" Standard for ETS; OSHA's Contradictory and Insupportable Position on ETS Does Not Comply With OSHA's Regulatory Framework and Undermines its Own Regulatory Position on Permissible Exposure Limits

OSHA's Proposed Rule acknowledges that the ordinary air in the non-industrial workplace contains substances that have been identified as "carcinogens," whether or not smoking takes place. 59 Fed Reg. 15983, 15998. The Proposed Rule presents a list of "typical pollutants" emitted from building materials, furnishings, appliances, office equipment and supplies. 59 Fed Reg. 15984. Many of the same constituents contained in the Proposed Rule's list of "tobacco smoke constituents" are found in OSHA's tables for emissions from office furnishings and materials. 59 Fed Reg. 15987-8. (See Table I) Benzene, for example, is emitted by paints, wood preservatives, cleansers, disinfectants, fuels, solvents, etc. Formaldehyde off-gases from particle board, pressed wood, resins, paneling, carpeting, upholstery, disinfectants, etc. Toluene is found in paints and other solvents, aerosol sprays, cleaners and disinfectants, air fresheners, fuels, etc. Benzo(a)pyrene is emitted from gas ranges, dryers, water heaters, and other combustion sources. Acetaldehyde, a substance in tobacco smoke described by OSHA as an "irritant," is found in adhesives,

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TABLE I

Tobacco Smoke Constituents Also Found in Emissions From Other Indoor Sources*

Emitted Pollutants	Indoor Sources
Acetaldehyde	Human Metabolism Preprinted Paper Forms
Acetic Acid	Preprinted Paper Forms
Acetone	Preprinted Paper Forms Typewriter Corrections Fluid
Acrolein	Preprinted Paper Forms
Ammonia	Electrophotographic Printers, Photocopiers & Related Supplies Microfiche Developers/ Blueprint Machines
Benzene	Adhesives Caulking Compounds Clipboard/Particle Board Floor and Wall Coverings Paint, Stains & Varnishes Electrophotographic Printers, Photocopiers & Related Supplies
Carbon Monoxide	Appliances Cooking Heating
Formaldehyde	Adhesives Caulking Compounds Carpeting Ceiling Tiles Clipboard/Particle Board Floor and Wall Coverings Paints, Stains & Varnishes Carbonless Copy Paper
Phenol	Computer/Video Display Terminals
Polyaromatic Hydrocarbons	Appliances

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Styrene	Carpeting Electrophotographic Printers, Photocopiers & Related Supplies
Toluene	Adhesives Clipboard/Particle Board Paints, Stains & Varnishes Computer/Video Display Terminals Electrophotographic Printers, Photocopiers & Related Supplies
Zinc stearate combustion products	Electrophotographic Printers, Photocopiers & Related Supplies

* Source: Proposed Rules, Federal Register, Vol. 59, No. 65, April 5, 1994, p. 15984, Table III-1 and Table III-2.

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cosmetics, office supplies, and emanates from other combustion sources. It also is an organic effluent that is emitted naturally by humans through metabolism.[11]

OSHA's Proposed Rule therefore seeks to eliminate exposure to substances if they are derived from ETS, while seeking only to reduce levels of precisely the same substances if they are derived from sources other than tobacco smoke. 59 Fed Reg. 16016, 16023-16027. Complete elimination of ETS will not eliminate exposure to substances imputed to it. OSHA cannot argue that the contribution of ETS to substances in the air of workplaces is "different" from, or greater than, contributions from other sources because OSHA does not present data on either ETS constituent levels or levels of constituents from sources other than ETS. Indeed, the Proposed Rule requests data "on the levels of these contaminants in non-industrial workplaces." 59 Fed Reg. 15985.

The elimination of ETS in the workplace cannot be achieved under OSHA's own regulatory framework. OSHA argues that tobacco smoke contains carcinogens and that no exposure to it should be permitted.* The list of constituents imputed to ETS by

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*. Yet OSHA sets a Permissible Exposure Limit for airborne asbestos fibers at 0.2 fibers per cubic centimeter of air. Asbestos exposures permitted by OSHA could conceivably attain levels equivalent to millions of fibers in the air of offices, public places or other workplace venues. Asbestos, of course, (continued...)

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OSHA (59 Fed Reg. 15979-80) contains suspected carcinogens currently regulated by OSHA through permissible exposure limits (PELs) (e.g., arsenic, benzene, chromium, nickel, formaldehyde, benzo(a)pyrene, etc.). (See Tables II-IV) OSHA cannot use substances with permissible exposures to demonstrate the "carcinogenicity" of ETS, and, at the same time, argue for its elimination.**

For the same reasons, OSHA cannot restrict its IAQ proposal to only the non-industrial workplace, while applying its de facto smoking ban to all workplaces, including both industrial and non-industrial venues. For the industrial worker, OSHA's plan

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*.(...continued)
is a Group A carcinogen that is not derived from ETS. Other designated carcinogens, such as benzene, chloroform, radon, styrene, carbon tetrachloride, etc. are also found in non-industrial buildings in the complete absence of ETS.

**. The Proposed Rule states that permissible exposure limits cannot be applied to ETS because (1) non-industrial environments do not have "administrative and engineering controls" of the industrial workplace (59 Fed Reg. 15973); (2) OSHA cannot quantify ETS exposure and therefore cannot set an exposure limit "that would eliminate significant risk" (59 Fed Reg. 16001); and (3) procedures for the identification of carcinogens "may not allow for the level of public input and policy review that is appropriate for this rulemaking . . ." (59 Fed Reg. 16001). What OSHA really means is that many of the constituents imputed to ETS already have existing permissible exposure limits, set at levels tens to thousands of times greater than any level contributed by ETS.[2-4, 8] Were OSHA to apply a PEL to ETS, its entire regulatory structure would collapse; a PEL for ETS would necessitate lowering PELs for individual constituents to conform with potential ETS exposure levels.

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TABLE II

Existing OSHA Permissible Exposure Limits
For Chemical Compounds Also Found in Tobacco Smoke*

Substance	ppm	mg/m^3
Acetaldehyde	200	360
Acrylonitrile; see 1910.1045	2 10 (ceiling limit)	
Arsenic, inorganic compounds (as As); see 1910.1018		0.01
Arsenic, organic compounds (as As)		0.5
Benzene; see 1910.1028	1	
Benzene; see Table Z-2 for the limits applicable in the operations or sectors excluded in 1910.1028[d]	10 25 (ceiling limit)	
Benzo(a)pyrene; see Coal tar pitch volatiles		
Cadmium (as Cd); see 1910.1027		0.005
Coal tar pitch volatiles (benzene soluble fraction), anthracene, BaP, phenanthrene, acridine, chrysene, pyrene		0.2
1,1-Dimethylhydrazine	0.5	1
Formaldehyde; see 1910.1048	0.75	
Hydrazine	1	1.3
Lead, Inorganic (as Pb); see 1910.1025		0.05
Nickel, metal and Insoluble compounds (as NI)		1
Nickel, soluble compounds (as NI)		1
2-Nitropropane	25	90
Styrene; see Table Z-2	100 200 (ceiling limit)	

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Vinyl chloride; see 1910.1017	1	

* Source: 29 CFR § 1910.1000 Table Z-1, unless otherwise noted.

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TABLE III

Existing OSHA Permissible Exposure Limits
For Particulate Phase Constituents of Tobacco Smoke*

Substance	ppm	mg/m^3
Aniline and homologs	5	19
Benzo(a)pyrene; see Coal tar pitch volatiles		
Cadmium (as Cd); see 1910.1027		0.005
Coal tar pitch volatiles (benzene soluble fraction), anthracene, BaP, phenanthrene, acridine, chrysene, pyrene		0.2
Hydroquinone		2
Nickel, metal and insoluble compounds (as NI)		1
Nickel, soluble compounds (as NI)		1
Nicotine		0.5
Phenol	5	19
Zinc oxide Respirable fraction		5
Zinc stearate Respirable fraction		5

* Source: 29 CFR § 1910.1000 Table Z-1, unless otherwise noted.

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TABLE IV

Existing OSHA Permissible Exposure Limits
For Vapor Phase Constituents of Tobacco Smoke*

Substance	ppm	mg/m^3
Acetic acid	10	25
Acetone	1000	2400
Acrolein	0.1	0.25
Ammonia	50	35
Benzene; see 1910.1028	1	
Benzene; see Table Z-2 for the limits applicable in the operations or sectors excluded in 1910.1028[d]	10 25 (ceiling limit)	
Butadiene (1,3-Butadiene)	1000	2200
Carbon dioxide	5000	9000
Carbon monoxide	50	55
Dimethylamine	10	18
Formaldehyde; see 1910.1048	0.75	
Formic acid	5	9
Hydrazine	1	1.3
Hydrogen cyanide	10	11
Methylamine	10	12
Methyl chloride; see Table Z-2	500 1000 (ceiling limit)	
Pyridine	5	15
Toluene	200 300 (ceiling limit)	

* Source: 29 CFR § 1910.1000 Table Z-1, unless otherwise noted.

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affords no protection from ordinary indoor air quality constituents found in the work environment. This means that the nonsmoking industrial worker, under OSHA's Proposed Rule, may be exposed to levels of chemicals 100 to 1,000 times greater than those found in either the non-industrial workplace or in ETS while, at the same time, the worker is not to be exposed to even a single wisp of tobacco smoke.*** This position is ludicrous and clearly displays OSHA's policy objective for the elimination of smoking at all costs. OSHA's own regulatory framework in fact prohibits the kind of policy represented in its Proposed Rule on ETS.

***. Thus, Ford Motor Company's submission to the OSHA RFI docket states: "For the most part, PTS/ETS and IAQ issues are not associated with significant air contaminant concentrations. In resolving this issue, government and management come head-on into a basic philosophical dilemma of should there be one set of air contaminant limits for the office and one for the shop floor. If one subscribes to the theory that PTS/ETS in the concentrations normally found in offices is carcinogenic, then one would also have to conclude that most workers in factories and garages are exposed to harmful levels of carcinogens. Even conservative epidemiological studies suggest that this type of epidemic does not exist in the American workplace." (3-447, 3-433)

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4. OSHA's Examination Of Workplace Exposure Studies On ETS Is Selective; The Studies Are Outdated And Are Not Representative Of Current ETS Exposures In The Workplace; The Data From The Proposed Rule's Discussion Of ETS Workplace Exposures Are Not Used In The Determination Of "Significant Risk" From ETS

OSHA's analysis of the data "available for . . . assessing exposure to ETS in the workplace" purports to establish average indoor levels of ETS and the percentage of average daily ETS exposure for nonsmokers in the workplace. 59 Fed Reg. 15987-91. The Proposed Rule discusses a select number of studies that measure nicotine and respirable suspended particles as markers for ETS in the air of workplaces. The studies are used to determine a range of average exposures to ETS. Four "human activity pattern studies" are used to establish OSHA's claim that the "workplace is a major location of ETS-exposure to nonsmokers." 59 Fed Reg. 15990.

The studies used in the Proposed Rule's discussion of ETS exposures are neither representative of, nor generalizable to, current levels of nonsmoker exposure in the workplace.

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(a) Human Activity Pattern Studies For Assessing Workplace Exposures To ETS Are Misinterpreted In The Proposed Rule; Such Studies Are Inherently Inaccurate And Not Representative Of Current Workplace Exposure Patterns

Human activity pattern studies are based upon an individual's recall of ETS exposure over a given period of time. Estimates of exposure are acquired through questionnaire responses and diary entries of study participants. Both the accuracy and the quantifiability of such "data," when compared to actual measures of ETS constituents in the air, have been challenged.[12-16] (See e.g., Coultas, et al. [Ex. 4-66], a study cited in the Proposed Rule). Two of the four human activity pattern studies cited in the Proposed Rule were conducted in the mid-1980s. Data for the third cited study were gathered in 1990 and a fourth study cited by the Proposed Rule is undated. 59 Fed Reg. 15988-90. The generalizability of the sample populations in each of the respective studies to the entire U.S. workforce under current exposure conditions is not addressed in the Proposed Rule.

The first study cited in the Proposed Rule is the California Activity Pattern Survey (CAPS), conducted in 1987-88. 59 Fed Reg. 15989. The Proposed Rule suggests that the California study indicates that "the most powerful predictor of potential exposure to ETS" is the workplace. OSHA claims that the study

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establishes that "77 percent of males and 85 percent of females were exposed [in the workplace] an average of 313 minutes and 350 minutes, respectively." 59 Fed Reg. 15987. However, close examination of the study itself and a subsequent published report [Ex. 4-168] indicates that the exposure time reported was not actual or continuous but total potential exposure time.[17] The study indicates that while 62 percent of the sample population responded that they were in the presence of smokers at some time during the day, only 27 percent were in work locations with smokers. The Proposed Rule fails to mention these important qualifications.

The Proposed Rule also does not discuss a more recent study of human activity patterns among Californians conducted by the U.S. EPA (1993).[18] Exposures to ETS were assessed in precisely the same way as in the CAPS study, namely, by personal recall diary. The study concludes that "less than 2 percent of the time was spent indoors or in transit in the presence of smokers." The report also notes that personal exposures to particles (daytime averages) did not differ significantly between individuals who reported exposure to ETS and those who did not.

The second population survey mentioned in the Proposed Rule is an undated study, the National Health Interview Study, conducted by the U.S. Centers for Disease Control. [Ex. 4-51]. According to the Proposed Rule, the "results suggest that at least

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19 percent of employed nonsmokers experience ETS exposure at work." 59 Fed Reg. 15989. The Proposed Rule characterizes the data in the CDC study as an "underestimate" because they are "based solely on self-reported information and the question was not very specific in defining immediate work area." 59 Fed Reg. 15995. This criticism, of course, applies to all the human activity pattern surveys relied upon by OSHA in its analysis of workplace ETS exposures.

A "re-analysis" of a 1986 study is cited as the third human activity pattern survey in the Proposed Rule. [Ex. 4-67]. 59 Fed Reg. 15989, 15995. The original study reported that the workplace was a source of ETS exposure for only 28 percent of all respondents.[19] According to the Proposed Rule, a "re-analysis" of a subset of the data from the Cummings, et al. study purportedly indicates that 49 percent of employed subjects (who report no ETS exposure at home), report ETS exposure at work. 59 Fed Reg. 15989. OSHA concludes from this that the workplace is a significant source of ETS exposure for nonsmokers. 59 Fed Reg. 15989. OSHA in fact adopts the 49 percent exposure figure as its upper bound estimate for nonsmoker exposure to ETS in all U.S. workplaces. 59 Fed Reg. 15995. Again, the applicability of those data -- compiled in 1986 -- to the entire nonsmoking workforce, is not addressed.

The fourth human activity study cited in the Proposed Rule was conducted in 1990 and is offered in support of OSHA's

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contention regarding "the widespread" exposure to ETS in the workplace. [Ex. 4-98]. The survey included 196 nonsmoking volunteers who provided estimates of their respective exposures to ETS during the work day. According to the Proposed Rule, the study indicates that more nonsmokers are exposed to ETS at work than at home. 59 Fed Reg. 15989. The Proposed Rule does not mention, however, that the volunteers for the study were recruited only from workplaces that permitted smoking. The sample obviously was not randomly selected and therefore cannot serve as the basis to OSHA's claim regarding the magnitude of ETS exposure in the workplace. Interestingly, the study also reports average exposures to ETS of approximately 30 minutes per day. Those data directly contradict OSHA's interpretation of exposure time from the CAPS study (350 minutes of ETS exposure a day). 59 Fed Reg. 15989.

The four "human activity pattern studies" selected by OSHA do not provide a consistent or complete dataset for estimating the extent of nonsmoker exposure to ETS in the workplace. The data are unverified by actual exposure measures and are not representative of current exposure conditions for ETS in the workplace.

Smoking in the workplace is currently regulated through a combination of private initiatives and government restrictions. The Proposed Rule does not consider the impact of smoking bans and

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other kinds of smoking restrictions on its estimates of nonsmoker exposures to ETS in the workplace. Although the Proposed Rule cites a survey conducted by the Administrative Management Society Foundation indicating that 25 percent of companies ban smoking, this and other information on smoking restrictions is not factored into OSHA's estimate of current exposure to ETS in the workplace. (59 Fed Reg. 16017). For example, the Proposed Rule does not discuss a 1991 Bureau of National Affairs survey of 833 companies regarding workplace smoking policies.[20] The survey reports that 85 percent of the companies responding had smoking policies in 1991, up from 54 percent in 1987 and 36 percent in 1986. Thirty-four percent of the surveyed companies had total bans on smoking, compared with just 7 percent in 1987 and 2 percent in 1986. Moreover, data from the survey indicate that smoking was banned in all open work areas in 80 percent of the responding companies in 1991, compared with a ban in open work areas in only 51 percent of companies in 1987. Obviously, the data indicate a severe tightening of restrictions on smoking in the workplace from 1986 through 1991. Other data indicate a continuation of the trends on smoking restrictions through 1994.[21, 22, 23] Smoking restrictions will of course reduce the percentage and extent of nonsmoker exposure to ETS in the workplace -- a point completely ignored in OSHA's analysis.

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The failure to utilize current data on ETS exposures in the workplace invalidates OSHA's conclusions that "the workplace is a major location of ETS exposure to nonsmokers" and that "exposure to ETS is pervasive." 59 Fed Reg. 15990, 16007. OSHA's analysis of "significant risk" for ETS assumes that the proportion of nonsmoking workers exposed to ETS in the workplace remains constant over time. 59 Fed Reg. 15996. That assumption is invalid. Changing patterns of smoking, decreased percentages of smokers,**** increased numbers of smoking restrictions and improved ventilation in the workplace will all affect estimates of nonsmoker exposure to ETS.

For an accurate representation of ETS exposure, OSHA must therefore determine (1) how many smokers are employed; (2) how many are permitted to smoke at work and under what conditions; (3) how many worksites are adequately ventilated; (4) and how (1)-(3) will affect actual ambient exposures to ETS. The Proposed Rule does not address any of these conditions.

****.For example, a recent analysis by the Centers for Disease Control reports that less than 27 percent of the adult population smokes, down from 33 percent ten years ago. (The Wall Street Journal, May 20, 1994).

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(b) The Proposed Rule's Discussion Of Ambient Levels Of ETS Constituents In The Workplace Is Selective And Incomplete; The Studies Cited Are Outdated And Unrepresentative Of Current Exposure Levels Reported For ETS in The Workplace

The Proposed Rule discusses a small and select group of ETS measurement studies from the home and other venues in order to provide an average estimate of ETS concentrations in the workplace. 59 Fed Reg. 15990-1. The studies cited by OSHA employ nicotine and respirable suspended particles (RSP) as markers for ETS exposures. According to OSHA's analysis, studies in offices report "a range of average nicotine concentrations" of 2 to 10 micrograms per cubic meter (ug/m^3), and a range for RSP exposures of 18 to 95 ug/m^3. 59 Fed Reg. 15990. The "average" exposure for nicotine is later "adjusted" to "5 to 10 ug/m^3" for the average worker and "50 to 100 ug/m^3" nicotine for the most-exposed individuals. 59 Fed Reg. 15991.

The Proposed Rule cites no published studies on ambient nicotine or RSP measures in the workplace after 1991. This omission includes two major literature reviews on the issue of ETS markers and measurement.[8, 24, 25, 26, 27, 28, 29] Other pre-1991 studies on nicotine and RSP measurements in the workplace, involving hundreds of offices and restaurants, are not considered in OSHA's analysis.[30-38] (See Table V) The latter studies, together with

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TABLE V

NONSMOKER EXPOSURE TO ETS
RECENT WORKPLACE AIR MONITORING STUDIES:
NICOTINE AND RESPIRABLE PARTICLES*

Study	Sample	Nonsmoker Exposure; (Mean; ug/m^3)	Comment
Hedge, et al. (1993) USA	27 office buildings Area sampling	2.4 ug/m^3 - nicotine 10.2 ug/m^3 - RSP/UVPM**, ***	Smoking restricted to offices and open-plan cubicle workstations; ("a nonsmoker may be exposed to the nicotine content of about 3 cigarettes per year.")
" "		3.8 ug/m^3 - nicotine 5.8 ug/m^3 - RSP/UVPM	Smoking restricted to areas with no local treatment of air; ("[nonsmoker exposure equivalent of] about 5 cigarettes per year.")
Lambert, et al. (1993) USA	7 restaurants	1.0 ug/m^3 - nicotine 27.8 ug/m^3 - RSP	Median levels for nonsmoking sections.
Broder, et al. (1993) Canada	3 office buildings	23 ug/m^3 - RSP 14 ug/m^3 - RSP	Before smoking ban. After smoking ban.
Holcomb (1993)	5 studies; 270 samples, offices and public buildings	0.3 ug/m^3 - nicotine	Review article.
	24 studies; 640 samples, offices and public buildings	45.9 ug/m^3 - RSP	
Turner, et al. (1992) USA	585 offices	0.17 ug/m^3 - nicotine 20.11 ug/m^3 - RSP	254 nonsmoking offices; ("Spillover from smoking areas to nonsmoking areas appears to be minimal.")
Guerin, et al. (1992)	Review of published nicotine data for offices, restaurants, public buildings and transportation facilities		"Nicotine concentrations are generally at least one and up to three orders of magnitude lower than the eight hour time-weighted permissible exposure limit of 500 ug/m^3 specified by OSHA for workplace exposure."
Oldaker, et al. (1992) USA	4 office buildings	2.75 ug/m^3 - nicotine 21 ug/m^3 - RSP/UVPM	Unrestricted smoking (2 buildings).

* Studies include 700 offices and 150 restaurants that were not considered in OSHA's proposed rule on ETS.

** RSP = respirable suspended particulate; UVPM = ultra-violet particulate matter (identifies ETS contribution to indoor levels of RSP).

*** OSHA's permissible exposure limit (PEL) for nicotine is 500 ug/m^3; the PEL for respirable particulate is 5,000 ug/m^3.

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Study	Sample	Nonsmoker Exposure; (Mean; ug/m^3)	Comment
Oldaker, et al. (1990) USA	125 offices	4.8 ug/m^3 - nicotine 27 ug/m^3 - RSP/UVPM	Average for both smoking and nonsmoking areas.
" "	82 restaurants	5.1 ug/m^3 - nicotine 36 ug/m^3 - RSP/UVPM	Average for both smoking and nonsmoking areas. "Estimated mean exposure for an eight-hour day in an office is 0.02 cigarette equivalent and for a 1-L meal in a restaurant, 0.003 cigarette equivalent."
Vaughan and Hammond (1990) USA	Office building 30 sample locations	2.0 ug/m^3 - nicotine 0.3 ug/m^3 - nicotine	Before smoking restrictions. After smoking restrictions.
Crouse, et al. (1989) USA	42 restaurants	5.9 ug/m^3 - nicotine 26.1 ug/m^3 - RSP/UVPM	"Average exposure to ETS is 50 to 1,000 times lower than exposure [to] a single cigarette."
Proctor, et al. (1989) UK	Office building 10 samples	0.6 ug/m^3 - nicotine 8.8 ug/m^3 - RSP/UVPM	Median levels.
Thompson, et al. (1989) USA	35 restaurants 6 food courts Personal nicotine monitor	5.4 ug/m^3 - nicotine 2.3 ug/m^3 - nicotine	Overall exposure.
Carson and Erikson (1988) Canada	31 offices	7.2 ug/m^3 - nicotine**** 24 ug/m^3 - RSP/UVPM	"Exposure estimated from mean nicotine and UV-PM results were 0.004 and 0.001 cigarette equivalent per hour, respectively."
Sterling and Mueller (1988) Canada	Office building 8 nonsmoking locations receiving recirculated air from a designated smoking area	1.0 ug/m^3 - nicotine 8 ug/m^3 - RSP	"Equivalent to 1/1800 of the nicotine [per hour] inhaled by actively smoking one cigarette."

**** Incorrectly cited in the OSHA NPR.

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studies on other markers for ETS exposures in the workplace, were, however, submitted to the OSHA RFI in 1992 (See: PM 3-1074).

The studies on ambient measures of nicotine in offices and restaurants that were omitted from OSHA's analysis report average levels of approximately 2.0 and 3.5 ug/m^3 nicotine, respectively. These exposures are equivalent to 1/400 to 1/200 of the nicotine found in a single cigarette. Averages for nonsmoking areas in workplaces with smoking restrictions are even lower, averaging less than 1 ug/m^3 nicotine, or about 1/1,000 of the nicotine in a single cigarette. This means that the typical nonsmoking worker would have to spend from 200 to more than 1,000 hours in an office, restaurant or public place in order to be exposed to the nicotine equivalent of a single cigarette.[26, 31, 32, 35-36]

Respirable suspended particles (RSP) are contributed by a number of sources, a point acknowledged in the Proposed Rule. 59 Fed Reg. 16003. OSHA states:

> People contribute millions of particles to the indoor air primarily through the shedding of skin scales. Many of these scales carry microbes, most of which are short-lived and harmless. Clothing, furnishings, draperies, carpets, etc. contribute fibers and other fragments. Cleaning processes, sweeping, vacuuming, dusting normally remove the larger particles, but often increase the airborne concentrations of the smaller particles. Cooking, broiling, grilling, gas and oil burning, smoking, coal and wood generate vast

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numbers of airborne indoor pollutants in various classifications.

Results of a 1993 study on particle exposures conducted by the U.S. EPA indicate that one hour of cooking activity generates approximately 100 times the particle concentration from a single cigarette.[39] The study reported that average percent contributions from "fine particle mass" (RSP) were: 10 percent from smoking, 68 percent from outdoor sources and 22 percent from unidentified sources.[39]

Special methods have been developed for the analysis of airborne particles that determine the relative contribution of ETS to total particles in the indoor air. One analytic technique employs ultraviolet particulate matter (UV-PM) as an indicator of the particle fraction contributed to the air by ETS.[8] Studies of UV-PM measurements in offices report ranges of from 27 to 44 ug/m^3 in areas where smoking is permitted.[24] Although indoor exposure limits do not exist for ETS-related particles, the World Health Organization has designated 100 ug/m^3 or less as an exposure level of "limited or no concern" for particles contributed by ETS.[40]

A recent review has summarized average levels of airborne particles from smoking and nonsmoking areas reported in studies performed in various settings.[24] The average particle concentration in the air of homes with smokers is about 27 micrograms per cubic

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meter higher than in homes of nonsmokers; offices and public places that permit smoking report average levels of particles that are about 22 micrograms/cubic meter higher than those reported for nonsmoking locations, and smoking areas of restaurants report levels that are 42 micrograms/cubic meter higher, on average, than nonsmoking areas.

In the largest single study of its kind, researchers monitored 585 offices for various ETS-related constituents, including particles.[29] The average level of particles recorded for 331 offices in which smoking was permitted was 46 ug/m^3, compared with an average of 20 ug/m^3 for 254 nonsmoking offices. The difference of 26 micrograms per cubic meter represents a level of particles that is far below that designated by the WHO as of "limited or no concern."[40]

The Proposed Rule contends that the contribution of RSP by smoking is much greater than that reported in studies employing the UV-PM method. The Proposed Rule combines the results of three studies of smoking and nonsmoking buildings conducted in the early 1980s. The combination of data from the three studies provides an average estimate of 262 ug/m^3 RSP in smoking buildings, compared with 36 ug/m^3 in nonsmoking buildings. 59 Fed Reg. 15990. An analysis identical to that presented in the Proposed Rule occurs in a 1992 paper written by two antismoking activists.[41] (The paper,

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however, is not referenced in the Proposed Rule.) Close examination of the three studies cited reveals that the data therein do not support the contention of the Proposed Rule. One of the studies measured RSP levels in pizzerias, bars, lodge halls, bowling alleys, church bingo games and fast food restaurants in 1980. The only office measurement reported was conducted under experimental conditions in a room in which levels of ETS were generated by seven smokers smoking 32 cigarettes in 49 minutes, yielding RSP values as high as 500 micrograms per cubic meter. One of the other studies cited included no office measurements. Such selective combinations of data only serve to confuse the issue. The studies clearly do not represent typical workplaces at 1994 levels of ETS exposure.

According to a comprehensive review undertaken by researchers at Oak Ridge National Laboratories, "chemical means for estimating the contribution of ETS to RSP have been evaluated, and suggest that ETS-RSP may comprise from 10 percent to 50 percent of indoor air RSP, in the field scenarios to which the methods have been applied."[8] Indeed, even a cursory examination of actual studies, consisting of hundreds of office, restaurant and other workplace situations, reveals that source-apportioned RSP levels due to ETS are at levels 5 to 10 times lower than those suggested in OSHA's Proposed Rule.

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(c) ETS Constituent Levels In The Workplace: An Interpretation

With the exception of nicotine, none of the substances used as markers for ETS in the air is characteristic of tobacco smoke. Other sources such as heaters, stoves, building materials, cleaning products and human activities often generate greater levels of those substances than ETS.[8] For example, studies indicate that automobile combustion, industrial processes, home heating and gas cooking are the predominant sources of carbon monoxide and nitrogen oxides in indoor air.[24] For this reason, neither constituent is an appropriate marker for ETS. Researchers report that there is little difference in ambient levels of carbon monoxide or nitrogen oxides in smoking and nonsmoking areas of workplaces and public places and in homes with or without smokers.[8, 24, 42-46] Levels of volatile organic compounds such as formaldehyde and benzene in the presence of smoking are often indistinguishable from levels reported in nonsmoking areas.[8, 32, 47-51] Studies that have examined ETS constituent levels of nitrosamines[52-54] also report minimal contributions to overall ambient air levels in homes, offices and public places.

Nicotine and RSP were selected by OSHA as the most suitable markers for assessing exposure to ETS. While nicotine is characteristic of tobacco smoke in the ambient air, it represents a gas-phase constituent and indicates nothing about the particle

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(RSP) phase of environmental tobacco smoke exposures. RSP, on the other hand, is not characteristic of tobacco smoke, but, if correctly sampled and analyzed, can provide approximations of exposure to the particle phase of ETS. Measurements of both nicotine and RSP are typically reported in terms of micrograms per cubic meter (ug/m^3). The absolute values of the levels measured, however, may not be meaningful to anyone other than scientifically trained personnel. It is therefore convenient to refer to a comparative or illustrative device in order to facilitate understanding about the levels of exposure to nicotine and RSP as reported in the scientific literature.

One particularly useful illustrative means for representing reported levels of nicotine and RSP in the ambient air is the notion of "cigarette equivalents." The use of "cigarette equivalents" as a heuristic device for understanding ETS exposures does not imply that active smoking and nonsmoker exposure to ETS are the same thing, or that mainstream smoke is "equivalent" to ETS. Nor does it mean that a measure of nicotine or RSP in terms of "cigarette equivalents" represents exposure to other constituents in ETS. However, the concept of "cigarette equivalents" offers a convenient means for quantitative comparisons of ETS exposures, and is a commonly used method for reporting measured levels in the published literature.

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For example, Oldaker, et al. reported average levels of nicotine exposure of 4.8 ug/m^3 for 125 offices.[31] The authors estimated exposures to nicotine for an eight-hour work day in an office to be equivalent to 0.02 of a cigarette. The authors also measured nicotine levels in 82 restaurants and the resulting average concentration was 5.1 ug/m^3; the exposure equivalent for a one-hour meal was 0.003 of a cigarette.

Carson and Erikson, cited in OSHA's Proposed Rule (59 Fed Reg. 15991), measured nicotine and RSP (UV-PM) in 31 offices.[55] The authors wrote: "Exposure estimated from mean nicotine and UV-PM results were 0.004 and 0.001 cigarette equivalent per hour, respectively." Proctor measured nicotine levels in smokers offices and reported that the average level of 3.1 ug/m^3 nicotine would provide an exposure equivalent of 0.018 to 0.010 of a cigarette over the course of a work-day.[32] Proctor wrote: "This means that a male nonsmoker would have to work in the smoker's office for over 11 weeks before being exposed to the equivalent nicotine as from smoking one cigarette." UV-PM/RSP levels in smokers offices were reported at 24 ug/m^3.[32] This would translate into an exposure equivalent of 0.013 cigarettes per day. Thus, Proctor: "This again would result in a male nonsmoker working in the smoker's office for 15 weeks before being exposed to the equivalent particulates as smoking one cigarette."

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Hinds and First, in one of the first studies of its kind, measured nicotine levels in various public places in 1975.[36] The venues included waiting rooms, restaurants, and cocktail lounges. Measured levels of nicotine averaged ranged from 1.0 to 10.3 ug/m^3, translating into equivalents of 0.001 to 0.009 cigarette per hour.

In 1993, Hedge, et al. measured nicotine in 27 air-conditioned offices under various smoking policies.[26] The authors write: "[A] nonsmoking office worker in open offices who does not spend time in designated smoking areas on average may be exposed to the nicotine content of about three cigarettes per year."

Although a suitable internal dose marker for ETS is not available, scientists have estimated that ETS-related particle uptake in the typical nonsmoker is approximately two-hundredths of one percent (0.02 percent) that of the active smoker.[56-58] Other scientists have estimated that ETS "inhaled doses" (based on particles) are 10,000 to 100,000-fold less than average doses calculated for active smokers.[59] The estimated nonsmoker "dose" is equivalent to actively smoking less than one cigarette over the course of a year.

Another scientist recently calculated estimated "retained doses" for nonsmokers using average exposures to various ETS constituents reported in the published literature.[24] The calculated

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dose for tobacco smoke particles, expressed in terms of cigarette equivalents, ranges from less than one-half to about four cigarettes per year for "light" and "heavily-exposed" nonsmokers, respectively.

(d) The Proposed Rule Does Not Utilize Actual Ambient Exposure Measures For ETS In The Workplace In Its Determination Of "Significant Risk"; Exposure Estimates From Epidemiologic Studies On ETS Are Used In The Determination Of "Significant Risk"; Exposure Estimates From Epidemiologic Studies Are Not Quantifiable; They Are Unreliable And Inconsistent With Actual Ambient Measurements Of ETS

In its analysis of "significant risk" for ETS, OSHA employs two epidemiologic studies on lung cancer and heart disease in nonsmokers. [Ex. 4-106; 4-139]. 59 Fed Reg. 15995. Exposures to ETS were determined in those studies through the use of questionnaires that, in turn, were dependent upon the accuracy of recall of exposure among those questioned. No actual ambient exposure measures were included in the epidemiologic studies. **OSHA's entire discussion of ambient measures of ETS exposures in the workplace is omitted from its significant risk analysis and replaced by the exposure estimates from two epidemiologic studies on nonsmoker lung cancer and heart disease.**

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One critical source of bias in epidemiologic studies on ETS is called "exposure misclassification bias" and arises from errors in reporting ETS exposures.[15, 60-65] As was suggested earlier, epidemiologic studies do not measure actual ETS exposures, but rather employ questionnaires to generate estimates of ETS exposure over long periods of time. Sometimes, the studies use exposure estimates given by spouses, children, or next-of-kin. The questionnaires used in epidemiologic studies on ETS vary and have not been validated or checked for accuracy. The National Research Council and other authors have criticized the use of questionnaires as representations of accurate and comprehensive exposure histories in ETS studies.[66, 67] Other studies demonstrate that questionnaires are an unreliable and inaccurate measure of ETS exposure.[14-16, 68-69]

Typically, questions regarding ETS exposures in epidemiologic studies are of the following sort: "Are you married to a smoker?"; "How long have you lived with the smoker?"; "About how many cigarettes a day did the smoker smoke in your presence?"; "About how many cigarettes a day did the smoker smoke?", etc. Answers to such questions vary widely across studies. For example, Friedman, et al. noted that, in their study, 30 to 35 percent of nonsmokers who were married to smokers reported no exposure whatsoever to ETS.[15] A more recent study reported a 36 percent exposure misclassification rate when ETS exposures determined by questionnaires were compared to exposures determined by ambient air

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measurements.[16] The authors of that study concluded: "The results . . . suggest that questionnaires lead to a large amount of misclassification which must be taken into account when assessing the effect of ETS exposure" . . . and that "an objective method to measure exposure which is sensitive, accurate, and reliable is needed to validate them." Another recent study that compared ETS measurements with questionnaire responses found that "the false report rate was high. Among those 575 participants reporting an average of 42 or more hours/week [exposure to ETS], 58 percent did not have a detectable cotinine level . . . ."[68]

Coultas, et al., in a study cited in the Proposed Rule [Ex. 4-66], report that "the levels of cotinine, respirable particles, and nicotine varied widely with self-reports of exposure to ETS . . . ."[12] A second study by Coultas, et al. reports that "personal exposure also varies with the nonsmoker's proximity to the smoker. Questionnaires cannot comprehensively and accurately assess each of these factors. Not surprisingly, we found that the questionnaire responses were poor predictors of concentrations of respirable particles and nicotine."[13] Schenker, et al. in another exposure assessment study, concluded that "self-reported exposure to ETS is an inaccurate measure of passive smoking in the occupational setting."[63]

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Pron, et al. noted in their study that "responses to initial screening questions used to detect a person's exposure to passive smoke were more reliable for residential than for occupational exposure . . . quantitative measures of exposure to passive smoke, i.e., number and duration of exposure, were even less reliably reported."[62] In another study by Coultas, et al., the authors reported that "responses concerning recent tobacco smoke exposure and urinary cotinine levels were correlated only to a modest degree." The authors "conclude that adults can reliably report whether household members smoked during their childhood, but information on quantitative aspects of smoking is reported less reliably."[69] Lerchen and Samet in 1986 reported that spouses of smokers correctly reported the smoking status of their spouses, however, "for the number of cigarettes smoked per day, wives tended to report 20 cigarettes smoked even when their husband smokes substantially more or less."[64]

OSHA argues, within the context of its analysis of "significant risk" for ETS, that home "exposures" to ETS are comparable to workplace exposures. It is argued that "in the absence of purely occupational data, information derived in environments other than worksites is also considered." 59 Fed Reg. 15994. The Proposed Rule cites a report prepared by Meridian Research in 1988 that contends that " . . . it is the exposure to environmental tobacco smoke, and not the environment in which that

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exposure occurs, that is the important risk factor." [Ex. 4-221]. The Proposed Rule continues: "Therefore, health effects observed and the risk estimates calculated from studies of the general population, or of selected subgroups, such as nonsmoking wives of smoking husbands, are relevant to the working nonsmoking population." 59 Fed Reg. 15994.

There are at least three distinct issues regarding OSHA's argument. First, OSHA equivocates on the phrase "exposure data." OSHA proposes to replace actual ambient air measures of ETS constituents in the workplace with exposures assessed by questionnaire response in epidemiologic studies. The foregoing analysis clearly indicates that questionnaire responses cannot quantitatively approximate, much less replace, actual measures of ETS constituents in the air of workplaces.

The second issue raised in OSHA's argument concerns the comparability of actual levels of ETS constituents in the home and in the workplace. OSHA contends (but does not prove) that the levels are comparable. 59 Fed Reg. 15994. Recent data, however, indicate that this is not the case. In a 1993 study of 96 nonsmoking, married women, ETS exposures were continuously monitored over a one-week period.[70] The results for actual measures of ETS exposures (using 3-ethenylpyridine and nicotine as markers for ETS) indicate that workplace exposure is "tenfold lower than

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home exposure due to living with a smoker." Average values for exposure to nicotine in the workplace indicate that it is a trivial source of (ETS) exposure (median value, 0.21 ug/m_3 nicotine, compared to the nicotine delivery of a single cigarette: 880 ug/m^3).[70]

The third issue raised in OSHA's argument is whether or not data from household "exposures" to ETS can be applied to the workplace. If current published data regarding workplace exposure to ETS constituents were not available, then perhaps OSHA could make its argument. However, current workplace exposure data are available, including seven major studies and two major review surveys of ETS measurements in workplaces, that could have been used by OSHA in its analysis. It is clear that OSHA chose not to use the data from those studies and reviews because, in most instances, the data reveal that ETS exposures in the workplace are minimal and often indistinguishable from background levels. Even in the complete absence of appropriate data on ETS measurements in the workplace, OSHA would still have to justify its argument for the application of exposure data from epidemiologic studies in the home to the workplace. As one scientist notes:

> Because workers not exposed to ETS and workers exposed to ETS in the same occupational group have not been medically followed for several years, there is no justification to apply the reasoning that because home exposure through spousal smoking might be associated with

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cardiopulmonary disease, then workplace ETS exposure can be expected to have a similar association . . . . Results of household exposure cannot be applied to workers . . . . Confounding factors related to ETS exposure in workplaces are different from factors influencing spouses and children in studies of household exposure. Dietary factors and household pollution may influence the incidents of spousal and childhood diseases. On the other hand, workers are exposed to industrial chemicals and outdoor pollutants as well as work-related stress. Familial patterns of inherited or acquired susceptibility to cardiopulmonary disease do not apply to occupational groups . . . . Unlike household exposure, workplace exposure can be monitored by good industrial hygiene practice.[71]

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